IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF JANICE CONNOR TAKEN AUGUST 13/14, 2013

BSC Counter Designation	**Objection**	**Plaintiffs Counter Designation to BSC Counter Designation**
jc081313, (Page 153:19 to 153:22) **153** **19 Q. And just from a timing standpoint, June of 2008** **20 means this came out before you got into your job -- your** **21 current job with Boston Scientific. Correct?** **22 A. That would be correct.**		**jc081313, (Page 153:15 to 153:18)** ***153*** ***15 Are you familiar with this document? Have you*** ***16 seen the NICE guidance document before?*** ***17 A. I am unfamiliar with it. I've heard about it,*** ***18 but I don't believe I've read it thoroughly.***
jc081413, (Pages 368:16 to 369:1) **368** **16 So this was an e-mail exchange between the** **17 physicians just speaking to the number of patients they** **18 have in the trial.**	**368:16-369:1 Non-Responsive**	

19 So this trial was approved by Boston Scientific **20 for I believe 100 patients, and they did complete the** **21 enrollment at 100 patients.** **22 So they may have been discussing this option,** **23 but they did complete the study with the same number of** **24 patients. They never submitted for more cases or** **369** **1 did anything outside of the original grant.**		
jc081413, (Page 370:21 to 370:24) **370** **21 Q. Okay. So there was part of that hundred that** **22 could be exposures. Right?** **23 A. The exposures that he refers to in here are --** **24 will be in the final data set.**		***jc081413, (Page 370:11 to 370:20)*** ***370*** ***11 And what he's saying is: Now I need to start*** ***12 racking up lots of cases, which means you want less*** ***13 numbers on top than you've got on bottom.*** ***14 A. So he didn't do this. So he's mentioning this,*** ***15 but he never did start to treat more patients outside of*** ***16 what he originally stated in his protocol, and neither*** ***17 did the other sites.*** ***18 Q. Well, they weren't through treating the first*** ***19 hundred yet, were they?*** ***20 A. At that time, they were not finished.***
jc081413, (Pages 376:1 to 377:12) **376** **1 Q. Now, going back to 512, the first page is where** **2 you're pulled into the e-mail chain. Right?** **3 A. Yes. At the top of the second page. Yes.** **4 Q. Well, you're at the bottom of the second page,** **5 it looks like. It says, "On Sunday, January 31st,** **6 Janice Connor wrote." Am I right?** **7 A. That e-mail is from me on January 31st or to** **8 me. Sorry. Cc'd. I'm sorry. Yes.** **9 Q. So Roger Goldberg writes you, One simple**	**376:1-377:12 Completeness**	***jc081413, (Page 377:13 to 377:16)*** ***377*** ***13 Q. Was that incorporated in this study?*** ***14 A. So this study is not yet -- the analyses is not*** ***15 yet complete, to my knowledge, so I'm not aware if they*** ***16 incorporated any of this.***

10 solution that come to mind is: Present the whole data **11 set as is and then present a secondary analysis,** **12 eliminating the first five cases for any surgeon who had** **13 no Uphold experience leading into the trial, and then** **14 also qualitatively explain the technique tips that is** **15 needed to be learned. Did I read that correctly?** **16 A. Yes.** **17 Q. You write back, "We can look into a formal** **18 learning curve analysis," and that's in quotation** **19 marks.** **20 A. I think I wrote that first and then Roger wrote** **21 back afterwards.** **22 Q. Okay. We need to quantify this more** **23 (definition, follow up through, et cetera). Any** **24 thoughts on numbers? Would this also include physicians** **377** **1 from other sites as well? It is a thought if we move in** **2 that direction.** **3 A learning curve analysis, what is that?** **4 A. So that is a separate statistical analyses** **5 where you correlate physician experience with their** **6 cases and their outcomes.** **7 Q. Okay.** **8 A. So meaning that you will look at physicians,** **9 numbers of physicians, and understand how many years,** **10 how many cases they have. So quantify their experience** **11 and then compare that to the patient's outcomes to** **12 assess if there are any significant differences.**		
jc081413, (Page 378:8 to 378:24) **378** **8 Q. You go on to say -- He goes on to say, "No**	**378:8-378:24 Completeness**	***jc081413, (Page 379:1 to 379:13)*** ***379***

9 additional treatments so far. One of them might require **10 a small revision (TBD later). Another looks like she's** **11 healing just fine with estrogen cream. I'm sure she'll** **12 continue with the study, as this is a well-known** **13 potential risk regardless of being in a study."** **14 And you write, Agreed. What was the treatment** **15 for these patients? Is the mesh still there? Are they** **16 discontinued from the study or are they still being** **17 followed?** **18 A. So obviously I was asking about the patients.** **19 So regardless of talking about statistics, I brought it** **20 back to the patients to ensure that they are -- their** **21 treatment is fine, which he did confirm. Obviously one** **22 patient is doing completely fine and the other one he's** **23 still following. But obviously there was no risk to** **24 him. As it is an accepted known risk of the procedure.**		***1 Q. Well, does the DFU say don't be in the first*** ***2 five patients that a surgeon does?*** ***3 A. The DFU talks about experience and training.*** ***4 There's no specific numbers which are not proven in the*** ***5 literature. There's not a definitive number.*** ***6 Q. Does the DFU say this is a hard procedure to*** ***7 learn to do?*** ***8 A. The DFU -- I'd have to refer back to it, but it*** ***9 does recommend training for physicians and to contact*** ***10 their representative if they need training.*** ***11 Q. Does DFU say anything about a learning curve or*** ***12 reference a learning curve analysis?*** ***13 A. I'd have to read back through the DFU to answer that question.***
jc081413, (Pages 461:19 to 464:1) **461** **19 Q. Tell the jury a little bit about yourself, your** **20 name, where you're from. Give them a little information** **21 about yourself.** **22 A. Sure. So my name is Janice Connor. I am from** **23 Massachusetts, so basically born and bred in** **24 Massachusetts. I work at Boston Scientific as the** **462** **1 clinical director right now. I've been with the company** **2 almost nine years in two different positions.** **3 I am married for about 14 years. I have two** **4 kids, an 11 and a half daughter and a ten-year-old son.**	**BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

Q. Thanks. We're going to talk a little bit more obviously about what you do at Boston Scientific, but before that, let's tell the jury a little about your educational background, where did you go to school, what are your degrees, that sort of information. **A. I graduated college in 1994. That was from the University of Massachusetts in Amherst, Massachusetts. My degree was in biology, so I have a bachelors in biology with a concentration in animal behavior, which started with animal research.** **Following University of Massachusetts, I got a degree -- my master's degree in science from the Massachusetts College of Pharmacy and Health Sciences in Boston. That degree is in regulatory affairs and health policy.** **Q. And prior to being employed at Boston Scientific, where did you work?** **A. So before Boston Scientific I was at Stryker Corporation. So I worked at a smaller division called "Stryker Biotech." So I was at Stryker Biotech, which** **463** **is in Massachusetts, for almost five years, about four and a half years, before coming to Boston Scientific.** **There, I was a manager in clinical affairs so I worked closely with the regulatory department, the marketing department, on medical device trials. So specifically we were managing trials on a product for spinal repair. So on spine fusion for older patients.**		

8 Q. And then when did you come to Boston Scientific 9 after being at Stryker? 10 A. So it was in early -- I'm sorry -- the end 11 of 2004. 12 Q. And when you came to Boston Scientific, what 13 was your position? What was your first position? 14 A. So when I came to Boston Scientific, I was a 15 clinical project manager in the endoscopy division. So 16 I reported to the director of clinical affairs, and I 17 was responsible for managing their medical device trials 18 on several endoscopic devices including biliary stents. 19 We did premarket trials as well as postmarket 20 trials, esophageal stents. So basically stents for GI, 21 gastrointestinal diseases. 22 Q. And how long were you in that part of the 23 company? 24 A. I was in that part of the company about four 464 1 years.		
jc081413, (Pages 464:8 to 475:22) 464 8 Q. And when did you move over to urology and 9 women's health? 10 A. So in April 2009 I had interviewed for the 11 director's position in the urology and women's health 12 division as a recommendation by my supervisor at the 13 time. I accepted that position and started in about 14 April 2009. 15 Q. What was your title when you came into that 16 division in women's health? 17 A. I was the director of clinical programs.	BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

Q. And is that still your current position? **A. Correct, yes.** **Q. Tell the jury what you do as the director of clinical programs in women's health.** **A. So my position as the director is basically to work cross-functionally with many different functions within divisions. What that basically means is I'm** **465** **responsible for working with the marketing group, who in the marketing group is responsible for product development, business strategy, and so forth. So I provide them information on clinical trials for our products. So I manage the clinical trials whether they're sponsored by the company, which means we basically design and manage them, or whether they're funded by the company, which means I deal with the physicians who are in the field using our products.** **I'm also responsible for learning about the patients in the field. So talking to the physicians, understanding any concerns they have with research, any interest they have in research, the unmet need, whether it's in the United States or globally.** **I also monitor the cadence, the publication cadence of all of our studies, whether they're sponsored by Boston Scientific or funded, which means I basically have a nice spreadsheet which tracks how these publications are going, when they're being published, where, in what journal, and by whom.**		

Q. Very good. You've thrown out a couple of terms I want to make sure the jury understands. When you talk about clinical research or clinical trials, in general what does that mean? What **466** **is a clinical research? What is a clinical trial?** **A. Clinical research is really the activity of conducting a study about a certain product, a certain patient over a length of time.** **So for example, if there was a question about the use of a device in a human patient -- so typically clinical research in my area is on humans -- we will design a protocol, which is a document that describes a background about the disease. So typically these are patients with a specific disease.** **And then we include information about the product. So whether it's a drug or device, a device within this division. We include information about how the device works, what our hypothesis is, which means are we trying to prove something with this product -- with this project or are we just trying to learn more information.** **We include information about study assessments, which are the blood tests or physical exams or any tests done on patients, whether they're for the study or a standard of care, which means the doctor would do them anyway.** **And the end result is that the data within**		

24 this study leads to a conclusion as to whatever 467 1 the hypothesis was, whether the device is, you know, 2 safe and effective a lot of times for new products or 3 current products or whether it explains certain risk 4 factors, why patients do better in some surgeries or 5 other. It's a long process to understand new products. 6 Q. Since you've been in the position in women's 7 health, has Boston Scientific funded and supported 8 clinical research related to its sling medical devices 9 to treat stress urinary incontinence? 10 A. So since I started in 2009, we have had a very 11 robust program for managing ISRs, which are 12 investigator-sponsored research studies. So these are 13 the funded studies that Boston Scientific provides 14 dollars for to independent researchers. So we've had a 15 robust program since 2009 that continues today with 16 increased funding through the years. 17 Q. And then same question with regard to Boston 18 Scientific's products to treat pelvic organ prolapse, 19 the Pinnacle and Uphold lines. 20 Since you've been in the director of clinical 21 programs, has Boston Scientific funded and supported 22 clinical programs to investigate those products? 23 A. For pelvic organ prolapse? 24 Q. Yes. 468 1 A. Absolutely. So there are approximately nine 2 active studies right now with many of those studies on		

the pelvic organ prolapse products. **Q. And even before you got to the women's health** **division in 2009, had Boston Scientific funded clinical** **research into its sling and pelvic organ prolapse** **medical devices?** **A. Yes. So there were sponsored studies as well** **as a good amount of funded studies, those ISRs that I** **was referring to.** **Q. Tell the jury a little bit about that. What's** **an ISR? What happens in an ISR?** **A. Sure. An ISR is, again, an investigator-** **sponsored research study. It's basically a well-known** **term throughout clinical research, which means that** **these are studies that a corporation does not sponsor.** **So typically in clinical research there's always** **somebody who's called a "sponsor," and that person is** **basically a person or entity that is in charge.** **For ISRs, that sponsor is a physician who's not** **an employee of the company, for the most part -- or for** **all parts, basically. So this physician in his clinic,** **his practice, has a research idea, submits this idea to** **the company.** **469** **There is a committee within Boston Scientific** **specifically for our division called the "research and** **education committee." So this committee reviews these** **grants -- we call them grants -- and decides, you know,** **reviews what the physician submitted to see if it's** **sound research. So it obviously has to fall along our**		

same process for a protocol and a hypothesis and study assessments and patient protection measures. We review that and decide, you know, is it aligned with our business, is it on-label, off-label, does it apply within the indication, does all that match up within the regulations, and fund or not fund those grants as the committee will decide. **Q. Do ISRs have a protocol?** **A. Yes.** **Q. And who generally puts the protocol together?** **A. So it's this physician. So that main physician who has that initial research idea is responsible for designing, writing, and submitting that research protocol.** **Q. And then -- In those ISR studies, do doctors enroll the patients then in the study?** **A. So these doctors that submit these grants, so the main physician is then responsible for either** **470** **finding additional sites or maybe he/she might enroll patients at his site.** **So most definitely once he has approval from Boston Scientific for this study, then it is his responsibility to recruit patients, which means that there might be patients that fit this research protocol in his practice.** **He will then during a patient visit speak with them about this research study and go through a process called the "informed consent process" and then enroll them if they are willing to be enrolled and if they fit**		

12 the study. 13 Q. And then are the doctors involved with 14 collecting the data on the patients that they enroll in 15 the study? 16 A. Yes. 17 Q. And then ultimately studies like this, are they 18 published in some fashion? 19 A. So for ISRs we actually have a contract 20 agreement between every sponsor. So again, these are 21 the independent physicians. So within that contract, it 22 specifically says these physicians are obligated to 23 publish their results. 24 So they are -- They do sign this agreement. 471 1 It's a negotiated agreement. And they all do agree to 2 publish their results as they can at the end of their 3 studies. Yes. 4 Q. And how are these results from these studies 5 published? 6 A. So these physicians, they will either submit 7 them to a conference. We had talked earlier about 8 several women's health conferences that are either 9 international or national. They can submit them for a 10 presentation to be on a podium. So that's one option. 11 They can submit them to be in a poster, which means the 12 data are just presented in a poster for people to read. 13 They can also submit them in a manuscript, 14 which means they will write up a paper, for the most 15 part up to ten pages of paper, and submit it to a 16 journal.		

And then for each of these situations, they're actually a peer-reviewed process. So when they submit these data, there are peers of this physician who will review the data, ask questions, reject or accept the information, ask for comments or edits as they see fit. **Q. And what is Boston Scientific's role in an ISR? Tell the jury where Boston Scientific fits in when these types of studies are conducted.** **472** **A. So we consider ourselves the funder. I don't know if that's a real word, but we basically will fund these grants. We do sign those contracts with the sponsors. We may make recommendations, whether it's in the protocol, in the manuscript, but these are recommendations only.** **The physicians ultimately are responsible for everything that happens with that study, whether it's enrolling patients, publishing data.** **Boston Scientific is given status updates on these milestones. So part of my responsibility is to contact these physicians routinely and ask them, you know, how many patients are enrolled. That's one of the main things that I ask because, again, we're looking to make sure they're compliant with our contract, which includes milestones.** **Q. You also mentioned Boston Scientific-sponsored studies. What are those and how do they differ from an ISR?** **A. When I use the word "sponsor" for Boston, that**		

21 means that our company is responsible for managing the **22 entire conduct of the study. So we typically will have** **23 a physician who is the lead for that study. So all** **24 studies that we sponsor have a group of physicians who** **473** **1 are involved in these studies but there's typically one** **2 who is the lead.** **3 This lead physician helps give us guidance on** **4 writing a protocol. So we will write the protocol along** **5 with guidance from this lead physician. We will select,** **6 along with this physician's assistance, other clinical** **7 sites, national, international, depending on the study.** **8 We typically will either manage data in our** **9 company or we'll hire an outside company that manages** **10 the data, which means we -- they build a database,** **11 typically it's on the Internet, where sites can enter** **12 these data in.** **13 And ultimately we're the ones who are** **14 responsible for conduct. So if anyone were to ever ask** **15 who's responsible, it's obviously us for these studies.** **16 We do work with this lead physician and the** **17 other physicians on a final publication. They are the** **18 authors on this paper and they do submit to a journal** **19 that we obviously will work with them to ensure that it** **20 gets to that final result.** **21 Q. Do both ISRs and Boston Scientific-sponsored** **22 research, are they both valid ways of conducting** **23 clinical trials?**		

24 A. Absolutely. So they are both based on -- they 474 1 have -- if you were listening to how I was describing 2 it, they are identical with the exception of who's in 3 charge. So it's really who's that first main point of 4 the conduct of the study. So they are run identically. 5 They are based on a study protocol. They have final 6 results. They have databases. They have sites. They 7 have patients. Everything is identical to it. So the 8 data in the end is most definitely valid to the 9 scientific community. 10 And I would say the majority of the studies 11 that you typically read about in journals or conferences 12 are those independent studies. But there are definitely 13 obviously a lot of sponsored studies, but they are valid 14 data for both. 15 Q. I want to talk about the medical devices that 16 you've been involved with in women's health to treat 17 stress urinary incontinence, Boston Scientific slings. 18 What are those devices? 19 A. So for our slings right now we have Advantage 20 sling, we have Lynx, Prefyx, Obtryx, and Solyx. 21 Q. And for medical devices that treat pelvic organ 22 prolapse, since you've been in the women's health 23 division, what are the medical devices that Boston 24 Scientific has offered for pelvic organ prolapse? 475 1 A. We call those the Pinnacle line, but those		

2 include the Pinnacle device, which is an anterior kit 3 and a posterior kit. That depends on the area of the 4 vaginal wall that is being treated. 5 We have an Uphold kit. 6 We also have a biologic called "Xenform," which 7 is a graft, a sheet of material. 8 There's also Repliform and Polyform. Those are 9 graft sheets. 10 Q. And did you also work on the Pinnacle product 11 as well, that medical device that Boston Scientific 12 offered to treat pelvic organ prolapse? 13 A. Yes. So my responsibility as a clinical 14 director is to manage clinical trials, and we've had 15 many trials on Pinnacle as well. 16 Q. For all of those devices, the sling devices 17 that you mentioned and the treatments, the medical 18 devices to treat pelvic organ prolapse, were those 19 cleared by the FDA prior to you coming into the women's 20 health division? 21 A. When I started in April '09, all of those 22 devices were currently on the market.		
jc081413, (Pages 476:1 to 478:2) 476 1 I want to talk a little bit about the studies 2 of Boston Scientific sling and pelvic organ prolapse 3 devices. 4 Are there studies in the published literature 5 on all of Boston Scientific slings and pelvic organ 6 prolapse medical devices? 7 A. Yes, there are. So one of my responsibilities 8 is to monitor that literature. So there are today over 9 50 studies published on our stress urinary incontinence	BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

devices as well as our pelvic organ prolapse kits. Q. And for each one of the devices that we mentioned, are there studies looking -- clinical trials, clinical studies looking at the safety and effectiveness of each one of those devices? A. Absolutely. So a lot of these studies, as I was explaining, for research they have -- they might have different objectives, so they might be studying these devices in a certain patient population. I know there's a study on women who are traumatized. There's a study published on sexually traumatized women. And they were using the device as -- that's an example of a certain population. They have studies on patients who have had previous failures for these devices. 477 So there are many studies of different patient populations, but they're all on the overall outcomes, which include the safety and effectiveness. Q. So for each one of Boston Scientific's slings -- Advantage, Lynx, Prefyx, Obtryx, and Solyx -- are there clinical studies looking at the safety and effectiveness of each one of those devices? A. Yes, there are. Q. And for Boston Scientific's treatments for pelvic organ prolapse -- Pinnacle and Uphold and Xenform and Polyform -- are there published clinical trials looking at the safety and effectiveness of those devices? A. Yes, there are. Q. And are there multiple studies looking at the		

16 safety and effectiveness of these slings and these 17 treatments for pelvic organ prolapse? 18 A. Correct. So we do have on file at Boston 19 Scientific a list of these studies. There are -- again, 20 they're included in our clinical documents to summarize 21 the safety and effectiveness of these devices. We also 22 use these studies to support these products for other 23 country approvals. So we do have many studies on file 24 in-house that we monitor that are published. 478 1 Q. I want to talk about some examples of these 2 studies.		
jc081413, (Page 491:1 to 491:12) 491 1 Q. Let's talk a little bit about the Polyform 2 product that Boston Scientific markets. What is 3 Polyform? 4 A. So Polyform is a mesh material. It's in a 5 graft. So it's the same material used in the slings, 6 but it's just not in a kit. So it can be used by the 7 physicians to treat pelvic organ prolapse. And they 8 actually fashion it into a certain size for their own 9 purposes. 10 Q. And are there published studies looking at the 11 safety and effectiveness of the Polyform device? 12 A. Yes, there are	BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc081413, (Pages 491:13 to 495:9) 491 13 Q. I want to talk now about the kits, the pelvic 14 organ prolapse kits, the Pinnacle kits, and the Uphold 15 kits that Boston Scientific markets. Let's start with 16 the Pinnacle kit.	491:13-495:9 FRE 403, Duplicative	Plaintiffs adopt and incorporate the previously designated testimony of Matthew Daives, MD, as set forth their counter designations to BSC's counter designations of Janice Connor's 2015 testimony.

(Exhibit Number 533 marked for identification) Q. Before we look specifically at Exhibit 533, are there published studies looking at the safety and effectiveness of the Pinnacle kits? A. Yes, there are. There are prospective, again following patients forward, and retrospective studies on the Pinnacle device. 492 Q. And what is exhibit -- Wait a second; get this pulled up real quick. (Pause) Q. What is this study? A. So this is a retrospective study. It was a Boston Scientific grant but managed -- completely managed by an independent physician. It was led by Peter Rosenblatt, whom we've spoke of before. He practices in Mount Auburn Hospital in Cambridge, Massachusetts. He had submitted to Boston Scientific for a grant to study the Pinnacle device retrospectively, along with many other centers within the United States. So he had, along with his partners in the study, enrolled over 200 patients. So there were 213 patients in this clinical trial who were treated with the Pinnacle kit and were followed for a little over two years. So followed for a mean of 27 months. Some patients were followed almost out to four years. The objective of the study was to collect data on mesh complications, also effectiveness endpoints,		

22 meaning the quality-of-life, anatomic outcomes, and so **23 forth, similar to all trials for these devices.** **24 So they had reported that for the** **493** **1 complications, the urinary tract infection, he's got a** **2 list of a few things, under 3 percent. Infection almost** **3 2 percent, voiding difficulty less than 1. And other** **4 less than 2 percent. No procedure-related adverse** **5 events. Required any intervention, majority of patients** **6 underwent incontinence procedures along with this** **7 Pinnacle device.** **8 Q. And did he look at mesh exposures in this** **9 particular study?** **10 A. He did. I believe he reported a mesh exposure** **11 rate of 4.2 percent and an overall complication rate of** **12 around 12 percent, 12.7 percent.** **13 Q. Would you read to the jury the last sentence** **14 there and his conclusion where he says "Thus."** **15 A. "Thus. in this retrospective study, long-term** **16 results support the safety and effectiveness of the** **17 Pinnacle PFR kit with low mesh exposure and no** **18 documentation or patient complaints of recurrent** **19 prolapse."** **20 Q. Go ahead.** **21 A. I forgot to note the recurrent prolapse.** **22 He doesn't specifically list a percentage here,** **23 but he does indicate no patients had recurrence. So the** **24 failure rate was very good for this study.** **494** **1 Q. Was that a reasonable conclusion based on the** **2 data in this study?**		

A. It was.
Q. And these are good results?
A. Yes.
Q. And was this particular study a Boston Scientific ISR?
A. It was, yes.
Q. And were these data presented?
A. It was. They were presented last year. I believe this is at AUGS, the American Urogynecologic Society. And he's also received acceptance for this to be in a manuscript, which is in the process of being printed.
Q. And when you say "a manuscript in the process of being printed," what do you mean?
A. Sure. What that means is that he basically -- as you can see, this abstract is very small. He used the same data and expanded into a ten-page paper, giving background on the device, a little more background on the objective of the study, and submitted this to a journal -- so there are medical journals in the United States -- and the journal accepted the publication. He's in the process of making a few minor edits per the

journal's request, which means it will be in print, in paper form, for people to access within this year.
Q. And in addition to this study that we've marked as Exhibit 533, are there other published clinical studies with Pinnacle, looking at the safety and effectiveness of the device?
A. There are, yes.
(Exhibit Number 534 marked for identification)

jc081413, (Pages 495:10 to 498:18) **495** **10 Q. Now, I want to talk about the Uphold device,** **11 Boston Scientific's Uphold device that's used to treat** **12 pelvic organ prolapse.** **13 What is Exhibit 534?** **14 A. Exhibit 534 is a published study in the journal** **15 of international urogynecology in 2012 by Dr. Vu and his** **16 coauthors of 115 patients. And this was at a single** **17 center. This is in Chicago, Illinois. These patients** **18 were treated with the Uphold device and were followed --** **19 I believe they're followed out to a year at a minimum.** **20 And they reported on their anatomic outcomes.** **21 He also had collected data on quality-of-life, which we** **22 talked about before. So one of those questionnaires was** **23 the pelvic floor distress inventory, which again** **24 patients record information on how their pelvic floor** **496** **1 disease basically impacts their daily life.** **2 They also had completed a questionnaire called** **3 the "surgical satisfaction questionnaire," which** **4 includes questions about will they recommend the surgery** **5 to their friends, to their mothers, daughters, and would** **6 they do the surgery again.** **7 Q. And what did the results from those --** **8 collecting that data on quality-of-life, what was that?** **9 A. So what the results show that 93 percent of the** **10 women who completed the surgical satisfaction** **11 questionnaire reported they were satisfied and they** **12 would choose the surgery again.**	**BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

Q. Did the study look at rates of mesh exposure? **A. They did. So they did measure rates of mesh exposure. So the rate in this clinical study was 2.6 percent.** **Q. Finally, could you read the author's conclusion in the abstract there.** **A. Sure. "This technique resulted in successful outcomes within both anterior and apical compartments with a low rate of mesh complications, and no cases requiring mesh removal or hospital readmission. High rates of satisfaction and improved condition-specific quality-of-life were observed."** **497** **Q. And those are good results and good conclusions?** **A. Those are good results, yes.** **Q. And do you agree that the author's conclusions flow from the data that they collected in the study?** **A. I do agree. So he had actually also looked at patients who've had a uterus and who had a previous hysterectomy, so patients without a uterus and those who do. And their rates are over 95 percent for their anatomic success. So that is very positive data.** **Q. And does this study establish that Boston Scientific's Uphold device is a safe and effective option?** **A. It does. Absolutely.** **Q. And are there other published studies that look at the Uphold -- Boston Scientific's Uphold device?** **A. There are, yes.** **Q. And are those studies published?**		

19 A. There are. There are many more upcoming 20 studies ongoing now and that are in the process of being 21 printed. 22 Q. Are there other studies that look at the Uphold 23 device that establish that it's a safe and effective 24 option? 498 1 A. Yes, there are. 2 Q. Has Boston Scientific stopped studying its -- 3 these devices, these slings and POP devices? 4 A. No. So we have -- as I mentioned before, that 5 robust ISR program, so that is still ongoing. 6 We've just approved recently over $2 million 7 grant for a research trial on Uphold LITE. So that is 8 ongoing. 9 There are many other studies on Uphold. For 10 example, there's a Pinnacle study ongoing as well. We 11 have a Solyx study that's being presented -- I think I 12 mentioned that -- in the fall. 13 We also have three very large studies, over 400 14 patients each, that will be -- one just started in the 15 Solyx sling with the Obtryx sling. That study started 16 and will go on for many years, outwards of five years. 17 And there's an Uphold study and there's a Xenform study. 18 So no. There's many studies ongoing now.		
jc081413, (Pages 498:23 to 499:3) 498 23 Q. Are there published studies, some that we've 24 looked at and others, that establish that Boston 499 1 Scientific's Pinnacle and Uphold devices are safe and	BSC has previously designated this testimony. Plaintiffs adopt an incorporate any	Plaintiffs adopt and incorporate their counter designations, if any.

2 effective options? 3 A. Yes.	objections as set forth in their counter designations, if any.	
jc081413, (Pages 501:5 to 503:5) 501 5 Describe for the jury how complications like 6 erosion or mesh removal are captured in clinical trials, 7 either ISRs or Boston-sponsored research. 8 A. So we did talk about the postmarket safety 9 surveillance. So that's the big process for all 10 complications, whether products are in a study, outside 11 of a study, in an ISR or a sponsored study. 12 So basically what that means is if it is a 13 clinical study, regardless of who is managing it, there 14 are data forms where data are reported on. And these 15 data typically get entered into a database within a 16 computer on the Internet. And whoever the sponsor is 17 analyzes, reviews that data. 18 If there were complications, that data then 19 gets reported to Boston Scientific. So that is an 20 obligation of the sponsor, whether it's us or an ISR. 21 If it's an ISR, it's in the contract that they're 22 obligated to report all complaints. 23 With regards to treatment for complaints -- so 24 on these clinical study forms there is an adverse event 502 1 form. Typically it's one spot where physicians will 2 record any complication that happens to a patient, 3 whether it's related or not related, procedure or 4 implant related. 5 There's also always a spot for them to record 6 the intervention. And typically there are examples on	BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

7 these forms. So it could be antibiotics or surgery or 8 no treatment. So there's always a spot for patients -- 9 I'm sorry -- for physicians to record what the treatment 10 was for any complication. 11 So an example of mesh extrusion, erosion 12 exposure, the same term would apply. If a physician 13 treats a patient, he or she will record that information 14 on the data, and that would go into the data analysis 15 and obviously get summarized in the final study report. 16 Q. So information about mesh removal or erosion or 17 exposures are summarized in even some of the abstracts 18 and publications that we looked at. Right? 19 A. Correct. 20 Q. And then if there are individual reports, will 21 Boston Scientific get those and report those to the FDA 22 if that's -- if they qualified under the FDA 23 regulations? 24 A. Yep. That's correct. 503 1 Q. So in terms of the Boston Scientific clinical 2 trials, information about mesh exposure, mesh 3 extrusions, and in some cases mesh removal are collected 4 in those studies. 5 A. Yes, they are.		
jc081413, (Page 511:19 to 511:21) 511 19 Q. Has Boston Scientific funded studies to 20 generate supportive data for its medical devices? 21 A. We have, yes.	511:19-21 FRE 401, 402 403	
jc081413, (Page 512:2 to 512:15) 512 2 And has Boston Scientific supported and funded 3 clinical studies that have resulted in supportive data	512:2-6 FRE 401, 402, 403	

4 for its Pinnacle devices like Pinnacle and Uphold? **5 A. Yes.** **6 Q. If you'd look over at Exhibit 488 for me,** **7 please.** **8 A. Okay.** **9 Q. And the plaintiffs' lawyers asked you a number** **10 of questions about this particular NICE document. Is** **11 this document the actual NICE guidelines?** **12 A. No. As I believe I tried to explain to the** **13 plaintiffs, this is not the actual guideline. It is** **14 titled "Understanding NICE Guidance." So this is almost** **15 a summary or a explanation of the NICE guidelines.**		
jc081413, (Pages 516:11 to 517:12) **516** **11 Q. Look at Exhibit 492 for me, please.** **12 Plaintiffs' lawyer asked you a number of questions about** **13 this particular -- this chart. And one of the risks of** **14 conducting a study, it lists potential for negative** **15 outcome. Do you see that?** **16 A. I do.** **17 Q. Is that true for any study that anyone** **18 conducts?** **19 A. Any study, anybody, any sponsor, any product.** **20 Q. And in your discussions about what clinical** **21 studies to do or not do, has Boston Scientific ever** **22 decided not to do a study because of a potential for** **23 negative outcome?** **24 A. No, we have not done that.** **517** **1 Q. Turn to the next page for me. The first** **2 clinical device mentioned here is Uphold, and there is a** **3 study design. Has Boston Scientific funded that** **4 particular study?**	**517:1-12** **FRE 401, 402, 403**	**Plaintiffs adopt and incorporate their counter designations to 435:25-439:18 of Janice Conner's April 21, 2015 testimony.**

5 A. So there are two studies ongoing right now, a 6 randomized controlled trial even of Uphold compared to 7 vaginal hysterectomy. 8 Q. And the second one also lists Uphold. Has 9 Boston Scientific, have they funded that particular 10 study? 11 A. Yes. The answer is yes. And this is 12 Dr. Mickey Karram's clinical study.		
jc081413, (Pages 517:17 to 518:20) 517 17 Q. And then finally on this particular chart, the 18 second Solyx, the single-arm study, has Boston 19 Scientific funded those Solyx studies? 20 A. So there are two already published studies -- 21 actually, three published studies and one ongoing right 22 now. Yes. 23 Q. So even though for that risk/benefit there is 24 an indication there for the potential for negative 518 1 outcomes, Boston Scientific has conducted those studies? 2 A. Yes. 3 Q. Turn over to 493 for me. This is a document 4 that's a draft from 1999. Is that right? 5 A. Yes. 6 Q. And this related to the ProteGen medical 7 device? 8 A. Yes. 9 Q. And were you even with Boston Scientific in 10 1999 when the ProteGen device was being marketed? 11 A. I was not, no. 12 Q. And the final bullet point on this particular 13 document talks about Boston Scientific will gather 14 clinical data to assess product performance in a broad	517:15-518:2 FRE 401, 402, 403	

15 spectrum of clinical situations. **16 Do you see that?** **17 A. I do, yes.** **18 Q. Has Boston Scientific done that with its slings** **19 and pelvic organ prolapse devices?** **20 A. Yes.**	**518:18-20** **FRE 403**	
jc081413, (Page 567:1 to 567:14) **567** **1 Q. The studies that you talked about to the jury** **2 that we marked as exhibits, do you personally believe** **3 those studies support the safety and effectiveness of** **4 Boston Scientific's SUI and pelvic organ prolapse** **5 devices?** **6 A. I do.** **7 Q. Are there also in addition to that other** **8 studies that are completely conducted independent of** **9 Boston Scientific on Boston Scientific's devices?** **10 A. There are. There are many studies that are** **11 independent, as I mentioned. Boston Scientific may not** **12 be aware of them until they're actually published or** **13 presented. So yes, we do have a list of those in our** **14 company.**	**567:1-14** **BSC has previously designated this testimony. Plaintiffs adopt an incorporate any objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

1. **Counter Exhibits to Counter Exhibits**
   a. 1323 to the Deposition of Janice Connor taken April 21, 2015

DATED: July 20, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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